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| 10/642,395      | 08/14/2003  | Michael S.H. Chu     | MIY-P01-024         | 9490             |

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EXAMINER

POUS, NATALIE R

ART UNIT PAPER NUMBER

3731

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/642,395             | CHU ET AL.          |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Natalie Pous           | 3731                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/22/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Specification***

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Priority***

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60286863, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 60286863 and 60274843 do support limitations regarding the guide tubes on the sling assembly,

referring to claims 19-34 of the present application. Accordingly, claims 19-34 are not entitled to the benefit of the prior applications 60286863 and 60274843.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-4, 7-13, and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Giesy et al. (US 5334185).

Regarding Claim 1, Giesy teaches delivery device for delivering an implant to anatomical site in a body of a patient, the device comprising; a handle (12), a shaft having proximal and distal ends (20) and attached to the handle at the proximal end

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(20a), a pusher tube (22) slidably fitted over the shaft and extending from the handle distally along a portion of the shaft, and a pushing mechanism (24) operatively interconnected with the handle for actuating the pusher tube distally along a portion of the shaft to deliver an implant (40) to an anatomical site.

Regarding Claim 2, Giesy teaches the delivery device of claim 1, wherein the pusher tube (22) and the pushing mechanism (24) are integrated into a single assembly.

Regarding Claim 3, Giesy teaches the delivery device of claim 1, wherein the handle (12) includes a first axially extending recess (14) and the pushing mechanism includes a first axially extending tongue (25) for slidably interfitting with the first axially extending recess (30).

Regarding claim 4, Giesy teaches the delivery device of claim 3, wherein the handle includes a first stop (14a) located at a proximal end of the first axially extending recess (14) and the first axially extending tongue includes a projection (24) located at a distal end for engaging with the first stop to limit axial motion in a distal direction of the first tongue relative to the handle.

Regarding Claim 7, Giesy teaches the delivery device of claim 3, wherein the first axially extending tongue includes a first projection (24) located at a distal end for engaging with a proximal end (14a) of the first axially extending recess to limit axial motion in a proximal direction of the first tongue relative to the handle.

Regarding Claim 8, Giesy teaches the delivery system of claim 1, wherein the pushing mechanism (24) slidably interfits (25) over the shaft (20) and includes a pusher button (24) for actuating the pushing mechanism.

Regarding Claim 9, Giesy teaches the delivery system of claim 1, wherein the pusher button (24) includes a reduced diameter portion for accommodating a finger of a medical operator (upper portion of button 24 tapers).

Regarding Claim 10, Giesy teaches delivery device for delivering an implant to anatomical site in a body of a patient, the device comprising, an implant for being delivered to an anatomical site in the body of a patient, and a delivery device including, a handle (12), a shaft having proximal and distal ends (20) and attached to the handle at the proximal end (20a), a pusher tube (22) slidably fitted over the shaft and extending from the handle distally along a portion of the shaft, and a pushing mechanism (24) operatively interconnected with the handle for actuating the pusher tube distally along a portion of the shaft to deliver an implant (40) to an anatomical site.

Regarding Claim 11, Giesy teaches the delivery device of claim 10, wherein the pusher tube (22) and the pushing mechanism (24) are integrated into a single assembly.

Regarding Claim 12, Giesy teaches the delivery device of claim 10, wherein the handle (12) includes a first axially extending recess (14) and the pushing mechanism includes a first axially extending tongue (25) for slidably interfitting with the first axially extending recess (30).

Regarding claim 13, Giesy teaches the delivery device of claim 12, wherein the handle includes a first stop (14a) located at a proximal end of the first axially extending recess (14) and the first axially extending tongue includes a projection (24) located at a distal end for engaging with the first stop to limit axial motion in a distal direction of the first tongue relative to the handle.

Regarding Claim 16, Giesy teaches the delivery device of claim 12, wherein the first axially extending tongue includes a first projection (24) located at a distal end for engaging with a proximal end (14a) of the first axially extending recess to limit axial motion in a proximal direction of the first tongue relative to the handle.

Regarding Claim 17, Giesy teaches the delivery system of claim 10, wherein the pushing mechanism (24) slidably interfits (25) over the shaft (20) and includes a pusher button (24) for actuating the pushing mechanism.

Regarding Claim 18, Giesy teaches the delivery system of claim 10, wherein the pusher button (24) includes a reduced diameter portion for accommodating a finger of a medical operator (upper portion of button 24 tapers).

Regarding Claim 19, Giesy teaches the delivery system of claim 10, wherein the implant comprises a sling (40) assembly having first (40a) and second (40b) ends.

5. Claim 34 is rejected under 35 U.S.C. 102(e) as being anticipated by Browning (US 6960160).

Browning teaches a delivery device for delivering an implant to anatomical site in a body of a patient, the device comprising, a handle (52), a shaft (54) having proximal

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and distal ends and attached to the handle at the proximal end, a first guide tube (30) having proximal and distal ends and attaches at the proximal end to a first end of a sling (30) assembly and slidably interfits over the shaft, proximal end first.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 5, 6, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giesy as a matter of design choice. Giesy teaches all limitations of preceding dependent claims 1, 3, 4, 10, 12 and 13 as previously described but fails to disclose wherein the handle includes a second axially extending recess substantially parallel to the first axially extending recess, and the pushing mechanism includes a second axially extending tongue for slidably interfitting with the second axially extending recess and a second stop associated therewith. Giesy discloses a first set of recess,



tongue and stop for the purpose of actuating the slidable tube. Since the applicant has not disclosed that adding a second set of actuating parts solves any stated purpose, and it appears that a single set of actuating parts as disclosed by Giesy would perform equally well as if a second set of actuating parts were present. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Giesy with a second set of actuation parts since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

8. Claims 10 and 19-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (US 6960160) in view of Makower et al. (US 5324306).

Browning teaches the following:

- an implant (10) for being delivered to an anatomical site in the body of a patient
- delivery device (50) including, a handle (52), a shaft (54) having proximal and distal ends and attached to the handle at the proximal end (fig. 15)
- an implant comprising a sling assembly (20) having first and second ends
- sling assembly includes a first guide tube (30) attached to the first end and a second guide tube (30) attached to the second end, and each of the first and second guide tubes are sized for slidably interfitting over a distal end of the shaft (50)
- shaft (50) has a conical tip (fig. 8c) at the distal end and at least one end of the first and second guide tubes is tapered (upper portion in fig. 8a) to accommodate the conical tip.

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- first and second guide tubes (30) are sized for interfitting, alternately, and one at a time, over the shaft (50) and abutting a distal end of the pusher tube (fig. 4).
- first guide tube (30) has proximal and distal ends and attaches at the proximal end to the first end of the sling assembly and slidably interfits over the shaft, proximal end first.

Browning fails to disclose a pusher tube slidably fitted over the shaft and extending from the handle distally along a portion of the shaft, and a pushing mechanism operatively interconnected with the handle for actuating the pusher tube distally along a portion of the shaft to deliver an implant to an anatomical site.

Makower teaches an implant introducer comprising a pusher tube (58) slidably fitted over the shaft (18) and extending from the handle (26) distally along a portion of the shaft, and a pushing mechanism (48) operatively interconnected with the handle (26) for actuating the pusher tube (58) distally along a portion of the shaft to deliver an implant (44) to an anatomical site in order to effectively eject the implant off of the shaft. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Browning with the pusher assembly of Makower in order to effectively eject the implant off of the shaft.

9. Regarding the limitation wherein the sling assembly is located at the proximal end of the guide tube, Browning teaches the device wherein the sling assembly is located at the distal end of the guide tube. It appears that the device of Browning performs the task of placing the sling equally well as that of the application wherein the sling is located at the proximal end of the guide tube. It would therefore have been

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obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Browning with the sling attached to the proximal end of the guide tube, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

10. Regarding the method claims, the combination of Browning and Makower teaches the following:

- slidably interfitting a first guide tube attached to a first end of an implant over a distal end and along at least a portion of a length of a shaft (Browning Column 2, proximate lines 60-65), positioning at least the distal end of the shaft in a body of a patient (Browning Column 6, proximate lines 36-45), sliding the first guide tube off the shaft to deliver a first portion of the implant into the body of the patient (Browning fig. 8), slidably interfitting a second guide tube attached to a second end of the implant over the distal end and along at least a portion of the length of the shaft, positioning at least the distal end of the shaft in the body of the patient, and sliding the second guide tube of the shaft to deliver a second portion of the implant into the body of the patient (Browning Column 19-28).
- wherein the implant includes a sling (10) for treating urinary incontinence (Browning Column 1, proximate lines 4-10).
- using a pushing mechanism to slide the first and second guide tubes off the shaft (Makower Column 6, proximate lines 44-55).
- the first and second guide tubes have proximal and distal ends, attach at their respective proximal ends to the sling assembly, and the method comprises

sliding the first and second guide tubes, proximal end first, over the distal end of the shaft (Browning fig. 9).

- delivering the implant to a mid-urethral position in the body of the patient (Browning Column 1, proximate lines 17-24).
- positioning the distal end of the shaft in the body of the patient intravaginally (Browning fig. 11).
- positioning steps for the first and second shafts are preformed before the sliding steps for the first and second steps (Browning figs. 8a-c).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP  
2/15/06



(JACKIE) TAN-UYEN HO  
PRIMARY EXAMINER

2/21/06